

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

LAURENCE F. DOUD III,

Defendant.

Case No. 19 Cr. 285 (GBD)

**MEMORANDUM OF LAW IN REPLY TO THE GOVERNMENT'S OPPOSITION TO  
DEFENDANT LAURENCE F. DOUD'S MOTION TO DIMISS COUNT ONE  
OF THE INDICTMENT (NARCOTICS CONSPIRACY)**

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Defendant Laurence F. Doud, by and through his undersigned counsel, Gottlieb & Janey LLP, respectfully submits this Memorandum of Law in Reply to the Government's Opposition (Doc. 16) to Mr. Doud's Motion to Dismiss Count One of the Indictment alleging Narcotics Conspiracy ("Count One").

**I. PRELIMINARY STATEMENT**

The Government's argument in opposition to Mr. Doud's motion to dismiss Count One is misleading on the law, concocts new legal standards to fit its needs, and distorts Mr. Doud's argument in an effort to obfuscate the key issues. Among other things, Mr. Doud is not claiming that he is "immune" from prosecution because of his status and Mr. Doud is not claiming that as "a pharmaceutical CEO [he] is categorically exempt from prosecution under Sections 841 and 846." (Doc. 16 at 9.) That is a clear perversion of defendant's moving papers. In that regard, the Government's argument that *United States v. Moore*, 423 U.S. 123 (1975) and its progeny are dispositive of Mr. Doud's argument that he is "immune" is misplaced. Even though that might make for interesting newspaper headlines, the Government has failed to join the issue.

Rather, Mr. Doud argues (accepting the Indictment as true) that his alleged conduct concerning the execution of suspect orders by customers that he allegedly knew were ultimately being diverted for illegitimate use—the gravamen of the factual allegations in Count One—does not violate the prohibitions of 21 U.S.C. § 841. Contrary to what the Government suggests, that is not a "sufficiency" argument; the point is that the Government, among other things, creates an untenable constitutional problem by attempting to prosecute Mr. Doud on the basis of factual allegations for which § 841 was not intended to be applied nor has ever been applied.

Further, the Government's opposition is devoid of any legal support for punishing the intentional disregard of suspect orders by an employee (such as Mr. Doud) of a wholesale distributor under § 841. While the Government banks on courts that have relied on *United States v. Moore*, 423 U.S. 123 (1975) to extend the application of Sections 841 and 846 to individual defendants with no medical background, these cases radically differ from the allegations in Count One of the Indictment.

In narcotics conspiracy cases involving illicit prescriptions, courts require a direct nexus between alleged conduct of the non-medical professional defendant (in this case, Mr. Doud) and a doctor or pharmacist who issued prescriptions outside the scope of professional practice and not for a legitimate medical purpose—a vital connection lacking in the Government's factual allegations in support of Count One. In an attempt to gloss over this critical aspect, the Government here attempts to impose two new standards on employees of registered wholesale distributors under Sections 841 and 846 in order to shoehorn Mr. Doud's alleged conduct. First, the Government contends that Section 841 applies to registered distributors when their conduct goes outside of the legitimate distribution chain. (Doc. 16 at 4.) Second, the Government attempts to extend medical responsibilities to all parties in the pharmaceutical distribution chain, regardless of their connection to doctors or pharmacists. However, *Moore* and its progeny do not extend that far and the Government fails to provide any legal support for this argument.

Moreover, a recent high-profile narcotics prosecution of a manufacturer executive underscores Mr. Doud's point: the Government must establish a direct connection between the alleged conduct of the non-medical defendant and the criminal doctor or pharmacist in a narcotics conspiracy case involving illicit prescriptions. On May 2, 2019, John N. Kapoor, founder and former Executive Chairman of Insys Therapeutics, Inc. ("Insys"), became the first chief executive

officer of an opioid manufacturer to be convicted at trial.<sup>1</sup> Specifically, Mr. Kapoor was convicted of racketeering conspiracy for conspiring with four other executives at Insys to bribe doctors to unnecessarily prescribe Subsys, a fentanyl-based pain medication provided by Insys, and defrauded insurers into covering these prescriptions.<sup>2</sup> While Mr. Kapoor was not convicted under Sections 841 and 846, Mr. Kapoor's bribery of doctors illustrates a fundamental deficiency in Count One here. In illicit prescription conspiracy cases, establishing a direct nexus to a doctor or pharmacist is paramount in negating a distributor's or a manufacturer's attenuated position on the pharmaceutical supply chain from the actual prescription process. Finally, with respect to the Constitutional Vagueness issue, the Government posits that Mr. Doud had "ample notice that conduct was illegal" (Doc. 16 at 18). However, the Government's presumption is confounding because Mr. Doud could not have had fair notice that his alleged conduct—conspiring with others to intentionally disregard suspect orders—violated 21 U.S.C. §§ 841 and 846. This is because the Controlled Substances Act ("CSA") separately addresses prohibitions and punishments concerning suspect orders<sup>3</sup> and no courts have recognized the intentional disregard of suspect orders by an employee of a wholesale distributor to fall under Section 841.

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<sup>1</sup> Janelle Lawrence, Riley Griffin, and Jef Feeley, *Insys's John Kapoor Is First CEO Convicted of Opioid Racketeering*, Bloomberg (May 2, 2019) <https://www.bloomberg.com/news/articles/2019-05-02/kapoor-is-convicted-of-racketeering-plot-to-drive-opioid-sales>.

<sup>2</sup> Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy, United States Department of Justice (May 2, 2019) <https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy>.

<sup>3</sup> See 21 U.S.C. § 832 and 21 U.S.C. § 842(c)(2)(D).

## **II. ARGUMENT**

### **A. Count One Of The Indictment Improperly Alleges A Violation of 21 U.S.C. §§ 841 and 846**

#### **1. The Government Misconstrues Mr. Doud's Basis For His Motion To Dismiss Count One And Attempts To Mandate A New Standard On Distributors To Fit Its Prosecution**

In an attempt to muddy Mr. Doud's Motion to Dismiss Count One, the Government incorrectly asserts that Mr. Doud believes he is categorically exempt from prosecution under Sections 841 and 846 due to his status as an executive of a registered wholesale distributor. (Doc. 16 at 9.) This simply is not true. Mr. Doud does not contend that he is above the law due to his position at RDC. In truth, Mr. Doud maintains that Count One is improper as his alleged execution of suspect orders by customers that he knew were ultimately being diverted for illegitimate use does not violate the prohibitions of 21 U.S.C. § 841. The Government failed to identify a single case in which an employee of a registered wholesale distributor conspired with others to intentionally disregard his responsibilities surrounding suspect orders. Instead, the Government attempts to dictate new standards on employees of distributors that have no basis in the law and relies on cases that have no application to the core of Mr. Doud's Motion to Dismiss Count One.

In its Opposition, the Government argues that the "CSA applies not just to street-level drug dealers, but also to pharmacists, doctors, drug distributors, and drug manufacturers *acting outside of the legitimate distribution chain.*" (Doc. 16 at 4.) (Emphasis added.) However, outside of being briefly referenced in *dicta* in *Moore*, a Supreme Court holding almost forty-four years old, no other courts have adopted the "legitimate distribution chain" standard in any Section 841 prosecutions. Further, there is no legal basis for the argument that failing to address suspect orders constitutes "acting outside of the legitimate distribution chain." If the failure to

comply with suspect order duties is tantamount to selling controlled substances outside of the legitimate distribution chain then either Section 841 would have specifically contemplated this aspect or there would have been no reason for recent amendments to the CSA categorizing suspect orders under a different regime.<sup>4</sup>

The Government ignores this reality and clings to case law rejecting various defendants' attempts for categorical exemption due to their respective status. Not only does the Government's reliance on these cases confound Mr. Doud's true argument, but the cases are not applicable here and do not join issue with Mr. Doud's argument. First, the Government cites to *United States v. Hill*, 589 F.2d 1344 (8th Cir. 1979) to stress that even an employee of a pharmaceutical manufacturer is not entitled to an exemption from Section 841 due to his position. *United States v. Hill*, 589 F.2d 1344, 1350 (8th Cir. 1979). (See Doc. 16 at 11.) However, the Government failed to include in its Opposition that the defendant in *Hill*, a regional sales manager, personally intercepted 16 different shipments of diet pills from customers and personally took possession of them. *Id.* at 1348-1349. Generally, the defendant would arrange for drugs to be shipped to a customer in his sales territory, then contact the customer and claim there had been a mistake concerning their order and that he would pick up the shipment. *Id.* at 1348. These drugs were never returned to the manufacturer and the companies' records indicated that they were paid for, although all of the customers to whom the orders were originally shipped denied making such payment. *Id.* Ultimately, the defendant intercepted these orders and took possession of them to covertly transfer the consignment of goods from one customer to another to qualify customers for quantity-based bonuses offered on a limited basis by his manufacturer employer. *Id.* at 1349.

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<sup>4</sup> See P.L. 115-271, § 3292(b) adding new 21 U.S.C. § 832, and the corresponding penalty structure under 21 U.S.C. § 842.



Outside of fact that the defendant in *Hill* and Mr. Doud were both employees of drug companies, the factual allegations against them could not be more different. Even accepting the allegations in Count One as true, the Government does not allege that Mr. Doud intercepted a shipment of drugs by RDC to its customers, took physical possession of the drugs, or rerouted them to other customers.

Additionally, the Government reliance on *United States v. Goldfine*, 538 F.2d 815 (9th Cir. 1976) and *United States v. Johnson*, 831 F.2d 124 (6th Cir. 1987) to emphasize courts' rejections of defendants' arguments for exemption from Section 841 due to their status as non-registrants is equally misplaced. (See Doc. 16 at 10.) Again, not only is Mr. Doud not relying on such a categorical exemption but these cases are also wholly inapplicable here. In *Goldfine*, the defendants used the pharmacies they ran and operated to personally traffic controlled substances through them by failing to maintain records of out of state cash orders and selling prescription drugs without a prescription. *Goldfine*, 538 F.2d at 818, 820 (9th Cir. 1976). In *Johnson*, the defendant, a medical center employee, closely supervised a resident doctor who regularly prescribed controlled substances of patients' choosing after either a perfunctory examination or none at all. *Johnson*, 831 F.2d at 126. Further, the medical center employee personally sold prescriptions outside of the clinic. *Id.* at 127.

Clearly, the defendants in *Goldfine* and *Johnson* were directly involved in an illicit prescription process by using their respective businesses to funnel drugs for non-medical purposes, personally taking possession of the drugs and identifying potential buyers. Here, even accepting the allegations in Count One as true, these are not the factual allegations in this case. Mr. Doud played no role whatsoever in the issuance of or the filling of any prescriptions and never personally sold controlled substances and the Government's Indictment does not allege as

much. Moreover, the crucial difference here is not just an issue of degree but one of substance about the allegations—the prosecutions of individuals under Section 841 involving persons directly involved with prescriptions, doctors or pharmacies.

## 2. The Government Attempts To Extend Medical Responsibilities To Everyone In The Pharmaceutical Distribution Chain, Regardless Of Their Connection To Doctors Or Pharmacists

The Government assigns medical responsibilities to all participants in the pharmaceutical distribution chain, regardless of their connection to doctors or pharmacists, to manufacture a basis to prosecute Mr. Doud under Sections 841 and 846. This is an inappropriate expression of the case law. Here, Mr. Doud is charged with violating 21 U.S.C. § 841 by conspiring to commit acts “**outside the scope of professional practice and not for a legitimate medical purpose**”—specific language from the Federal Regulations concerning doctors’ and pharmacists’ obligations to issue legitimate prescriptions. *See* 21 C.F.R. § 1306.04<sup>5</sup>. (Emphasis added.) In support of this expansion of medical obligations, the Government asserts “that **people in the pharmaceutical distribution chain are only authorized to distribute controlled substances for legitimate medical purposes**...When someone in that system knowingly distributes controlled substances not for legitimate medical purposes that action violates Section 841 regardless of where within the chain that person sits.” (Doc. 16 at 15.) (Emphasis added.) However, this is mere lawyer argument without statutory or legal support. It is more than obvious that not everyone along the supply chain has a professional practice in medicine or pharmacy, which is what this language requires under the applicable regulations, and not

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<sup>5</sup> “A prescription for a controlled substance to be effective must be issued **for a legitimate medical purpose** by an individual practitioner acting in the **usual course of his professional practice**.” 21 C.F.R. § 1306.04. (Emphasis added). According to the Federal Regulations, the responsibility for the proper prescribing and dispensing of controlled substances, does not rest with an employee of a wholesale distributor but with “...the prescribing practitioner... [and] a corresponding responsibility rests with the pharmacist who fills the prescription.” *Id.*

everyone in the supply chain is close enough to the medical or pharmacy application to render or directly influence a prescription.

In fact, as we have discussed and the case law shows, courts have only extended these responsibilities to non-medical professional defendants when there has been a direct nexus between the defendant and a doctor or pharmacist issuing illicit prescriptions. Indeed, the Government's own case law underscores these limited circumstances. (*See* Doc. 16 at 14-15 relying on *United States v. Quinones*, 635 F.3d 590 (2d Cir. 2011).) In *United States v. Quinones*, 635 F.3d 590 (2d Cir. 2011), the Second Circuit recognized that “[a] lay defendant...may be convicted of unlawful distribution of a controlled substance where the defendant relies upon a doctor’s prescription that he knows or reasonably should have known was invalid. *Quinones*, 635 F.3d at 594. While the Government would have this Court believe that *Quinones* mandates that everyone in the pharmaceutical distribution chain must uphold medical standards expected of doctors and pharmacists, this case actually underscores Count One’s key deficiency—failing to allege a direct conspiracy between Mr. Doud and the medical professionals who were actually responsible for illicitly prescribing the controlled substances provided by RDC.

In *Quinones*, non-registrant owners of an online pharmacy were “prosecuted for conspiring with, and aiding and abetting, medical professionals...to distribute controlled substances outside the usual course of professional practice.” *United States v. Quinones*, 536 F. Supp.2d 267, 273 (E.D.N.Y. Feb. 19, 2008). More particularly, Internet users who searched for a prescription medication would be directed by a search engine to defendants’ website. *Id.* at 592. Once at the website, customers would select his or her preferred drug, payment information and delivery instructions, and then fill out a brief medical questionnaire which was transmitted to

a doctor who would approve or disapprove of the order without any interaction whatsoever with the customer. *Id.* The defendants personally selected these doctors and paid them per questionnaire reviewed. *Id.* at 592-593. Finally, after a doctor approved an order, it would be sent to a licensed physical pharmacy controlled by defendants that filled the prescription. *Id.* at 593. While the defendants in *Quinones* did not have any medical knowledge, they were clearly involved in every aspect of an illicit prescription operation. In contrast, Mr. Doud interacted with no patients, no doctors, and no pharmacists and was never involved with the issuance of or the filling of a prescription and the Indictment does not so allege. Moreover, Count One does not even allege that Mr. Doud conspired with *anyone outside* of RDC. Rather, it merely alleges that Mr. Doud conspired with other members of senior management at RDC (Indictment ¶ 4) and with “others known and unknown...to violate the narcotics laws of the United States.” (Indictment ¶ 20.)

As Mr. Doud stated in his moving papers, we cannot identify any instance in which a Section 841 case involving illicit prescriptions and a non-medical professional defendant did not have a direct connection to a doctor or pharmacist who issued prescriptions outside the scope of professional practice and not for a legitimate medical purpose. While the Government insists that Mr. Doud’s general knowledge that RDC’s customers were selling the company’s product for unlawful purposes is enough (*see* Doc. 16 at 12.), in truth, *Quinones* illustrates that non-medical professionals being prosecuted under Sections 841 and 846 must be shown to be involved in some direct capacity in the illicit prescription process at issue.

#### **B. Sections 841 Is Unconstitutionally Vague As Applied To Mr. Doud**

The Government’s claim that Mr. Doud had “ample notice that his conduct was illegal” is simply unfounded. (*See* Doc. 16 at 18.) As the gravamen of Count One’s allegations is Mr.

Doud's execution of suspect orders and failure to report them (*see* Indictment at 9-10, 14.), the Government misses the point. It is not enough that Mr. Doud simply had generalized notice that any individual could be liable under Section 841 for the commission of a drug offense. (Doc 16. at 19.) Rather, in a void for vagueness analysis, "the touchstone is whether the statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal." *United States v. Lanier*, 520 U.S. 259, 267 (1997). Neither the CSA nor the Federal Regulations provide sufficient notice that conduct surrounding the execution of suspect orders by an employee of a registered wholesale distributor violates 21 U.S.C. § 841. Additionally, no court has ever applied the narcotics statute of 21 U.S.C. § 841 to the conduct at issue here.

While the Government imagines that "courts considering prosecutions of individuals employed within the legal controlled substances distribution chain consistently have concluded that any person who knowingly distributes controlled substances outside of that legal chain...is subject to prosecution under Sections 841 and 846[,]" the Government has not identified a single case in support of the legitimate distribution chain proposition introduced in *dicta* in *Moore*. (*See* Doc. 16 at 19.) In the forty-four years since the Supreme Court's holding in *Moore*, no courts have adopted this analysis in connection with a Section 841 prosecution. Accordingly, while Mr. Doud has not identified a single case holding that Section 841 or 846 is unconstitutionally vague as applied to any defendant, this is because Section 841 has never been specifically used to prosecute the intentional disregard of suspect orders by an employee of a wholesale distributor. Additionally, the Government primarily cites to cases wholly unrelated to Section 841 prosecutions. The few cases that do involve Section 841 do not have any application to Count One's allegations as the defendants were either doctors, an employee of a

pharmacy or individuals directly involved in illicit prescription schemes of doctors and pharmacies.<sup>6</sup> (Doc. 16 at 20.)

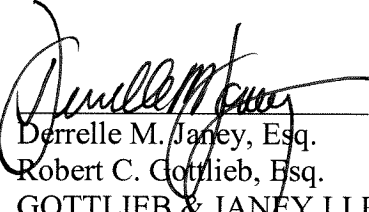
Given the complete lack of precedent surrounding suspect orders, it is inconceivable how Mr. Doud could have had fair notice that his alleged conduct violated 21 U.S.C. §§ 841 and 846. Thus, section 841, as applied to Mr. Doud here, is unconstitutionally vague.

### III. CONCLUSION

For the foregoing reasons, in addition to the arguments submitted by defendant Laurence F. Doud in his initial motion papers, Mr. Doud respectfully requests that the Court grant his pretrial motion to dismiss Count One of the Indictment alleging Narcotics Conspiracy.

Dated: New York, NY  
October 29, 2019

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<sup>6</sup> See *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975) (doctor illicitly dispensing prescriptions); *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973) (doctor illicitly dispensing prescriptions); *United States v. DeBoer*, 966 F.2d 1066 (6th Cir. 1992) (employee of pharmacy illicitly filling prescriptions); *United States v. Birbragher*, 603 F.3d 478 (8th Cir. 2010) (online company contracted to solicit prescription orders for doctors who did not verify customer identities, review medical records, or conduct physical examinations); and *United States v. Quinones*, 536 F. Supp.2d 267, 273 (E.D.N.Y. Feb. 19, 2008) (online company paying doctors to prescribe prescriptions from their pharmacies without any patient interaction and based on a brief customer questionnaire the company provided).